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Discussion

Dr Juan Carlos Chachques *(Paris, France).* I think that this is a very interesting approach. We know this kind of therapy has limitations because of work in dynamic cardiomyoplasties during several years. This device existed 4 or 5 years ago. You have now a 2-month follow-up without histologic study. We know that foreign materials positioned around the heart can induce fibrosis and, secondarily, compression. Do you have histologic evidence at long term that this device cannot induce high fibrosis and then diastolic function limitation?

Dr Pilla. In this study, which was terminated at 2 months, there was no difference in end-diastolic pressure. There was actually a slight improvement in dP/dt_{min} in the CSD group; also τ, the time constant relaxation, was also slightly improved in the CSD group. So with respect to diastolic dysfunction, there didn't seem to be any at 2 months. We are performing ongoing studies in which the animals will actually go out to 3 months to look at such issues as diastolic function and also the histologic and pathologic changes that occur in the myocardium.

Dr Chachques. This is not long term. Okay, we agree.

Dr Pilla. Relatively long term.

Dr Michael A. Acker *(Philadelphia, Pa).* Just a follow-up of your question. In a different model, Hani Sabbah from Henry Ford has looked at his heart failure dogs as late as 1 year histologically, and there is the same thin scar formation as is present at 2 months. So it does not appear in about 6 animals that there was an ongoing process.

Clinically now there are patients now who have had this jacket placed for more than 2 years, although again not for acute MI but for chronic dilated myopathies. There is no evidence in close to 100 patients to date of constriction developing physiologically, and, a few patients are out over 2 years. Will this develop in 5 years, or 10 years? We don't know. But there is not any evidence at this time in animal or in human trials.

Dr Stephen Westaby *(Oxford, UK).* Can you just speculate quickly how you would take this forward clinically, because it is very difficult to see how you would decide to do a thoracotomy and place this device in a patient who has just had a myocardial infarction.

Dr Pilla. Actually, they are currently working on minimally invasive techniques to position the CSD for such reasons as avoidance of a thoracotomy after MI. So they are addressing those issues, because we do have the same concerns.